REMARKS

Claims 1-4 and 27 are currently pending and under consideration. Favorable reconsideration of the subject application is respectfully requested in view of the following remarks.

Withdrawal of Rejections Under 35 U.S.C. § 102(b) and Request to Remove Finality

Applicants thank the Examiner for his withdrawal of the previous rejections under 35 U.S.C. § 102(b), in light of the Amendment submitted December 3, 2003.

However, Applicants respectfully request that the Examiner withdraw the finality of the present Office Action. As stated in the M.P.E.P., "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information [timely] submitted in an information disclosure statement." M.P.E.P. § 706.07(a). Applicants submit that the Examiner has introduced a new ground of rejection based upon a publication not previously cited by the Examiner or in an information disclosure statement, namely Deng *et al.* Furthermore, Applicants submit that this basis of rejection was not necessitated by Applicants' prior Amendment, which merely added an additional feature to the claims. Accordingly, to the extent that Deng *et al.* is relevant to the instant claims, it would have been relevant to the claims prior to their amendment. Thus, Applicants respectfully request that the finality be removed.

Objection to the Specification

The Examiner has objected to the title of the invention as being not descriptive. Without acquiescence, the title has been amended to more specifically recite certain aspects of the claimed invention. Applicants submit that the title is now clearly descriptive and request that this basis of rejection be withdrawn.

Rejection Under 35 U.S.C. § 102(b)

Claims 1 and 27 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Deng *et al.* More specifically, the Action asserts that Deng *et al.* discloses culturing *Mycobacterium smegmatis* in glycol-alanine-salts medium in the presence of Tween 80 and ethambutol, a structure modifying compound and, thus, teaches a general enrichment media comprising a structure modifying organic chemical, as presently claimed.

Applicants respectfully traverse this basis of rejection and submit that the cited reference fails to anticipate the presently claimed invention. Applicants note that for a prior art reference to anticipate a claim, it must disclose each feature of the claimed invention. *Verdegaal Bros. V. Union Oil Co. of California,* 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants submit that the present invention is drawn to inventive compositions and methods for incubating microorganisms to expose antigenic epitopes therein, thus permitting detection agents increased accessibility to and facilitating detection of the microorganisms. Thus, the compositions of the invention comprise a structure-modifying organic chemical, which acts to expose antigenic epitopes. As described in the instant specification, this structure modifying organic chemical is an organic chemical capable of altering the composition of the cell wall of an organism, such that specific and conserved ligands are exposed, while permitting the microorganisms to multiply to optimal levels, which is important to allow the organism to grow to sufficient numbers for detection (page 8, lines 11-13; age 9, lines 5-6, and page 9, lines 15-20).

Applicants submit that Deng *et al.* fails to teach a composition comprising a structure modifying organic chemical, as recited in the instant claims and, therefore, fails to teach each element of the claimed invention, as necessary to establish a case of anticipation. Specifically, Applicants submit that ethambutol inhibits microorganism growth and, therefore, does not meet the definition of a structure modifying organic chemical of the invention. Ethambutol is an antibiotic that is used to kill the bacteria that cause tuberculosis. Although the mechanism of action of ethambutol is uncertain, it is thought to block the ability of tubercle bacilli to build and maintain cell walls and inhibit RNA synthesis, resulting in impaired cellular metabolism and multiplication. Indeed, Deng *et al.* explicitly states that "ethambutol strongly inhibited growth under the conditions used" (page 697, first paragraph; emphasis added).

Clearly, treatment with ethambutol dramatically inhibits cell growth and, therefore, does not permit microorganisms to multiply to optimal concentrations, as described in the instant application.

In addition, Applicants submit that ethambutol is specific to the mycobacteria, while all other bacteria, fungi, and yeasts are not susceptible to the drug (Deng *et al.*, page 94, second paragraph). Accordingly, even if ethambutol did not substantially decrease cell growth, the skilled artisan would not be motivated to use ethambutol in the claimed methods, which are designed to be used to detect a variety of different microorganisms. Indeed, the skilled artisan would appreciate that ethambutol could not be used as a structure modifying organic compound according to the invention. Clearly, if a microorganism other than mycobacteria was being detected, then ethambutol would have no effect on the structure of this microorganism and would be essentially useless according to the invention.

In light of these remarks, Applicants submit that Deng *et al.* fails to teach a structure modifying organic chemical and, accordingly, fails to anticipate the claimed invention. Therefore, Applicants respectfully request that this basis of rejection be withdrawn.

Rejection Under 35 U.S.C. § 103(a)

Claims 1-4 and 27 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Deng *et al.*, in view of Marino *et al.* and Ohyama *et al.* Specifically, the Action asserts that Deng *et al.* teaches a composition comprising a detergent and a structure modifying compound, while acknowledging that Deng *et al.* fails to teach the specifically recited compounds, 2,4-dinitrophenol and carbonyl cyanide-m-chlorophenyl hydrazone. Rather, the Action asserts that Marino *et al.* and Ohyama *et al.* remedy this deficiency by teaching 2,4-dinitrophenol and carbonyl cyanide-m-chlorophenyl hydrazone, respectively. The Action concludes that it would have been obvious to one of ordinary skill in the art to modify the procedures taught by Marino *et al.* and Ohyama *et al.* by adding a detergent to the growth medium, as set out in Deng *et al.*, in order to avoid clumping.

Applicants respectfully traverse this basis of rejection and submit that the Action fails to establish a *prima facie* case of obviousness. More specifically, the Action fails to

establish any motivation to combine the cited references to achieve the claimed invention. As established by the courts and enunciated in the M.P.E.P., "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention when there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." M.P.E.P., 8th Ed. § 2143.01. Furthermore, the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination (*see, e.g., In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992)).

In the present case, none of the cited references teach, suggest, or would motivate the skilled artisan to combine the references to achieve the claimed invention. Indeed, the Action has pointed to no such teaching in any of the references, and Applicants submit that knowledge in the art related to microorganism culture media also provides no basis for combining these references. Rather, the cited references are directed to vastly different subject matter and describe medias formulated for the growth of different microorganisms. Specifically, Deng *et al.* describe the growth of *Mycobacterium smegmatis* and, therefore, use a media designed for *Mycobacterium*. It is well-established in the art that optimal media for culturing *Mycobacterium* are complex medias containing Tween. In contrast, Marino *et al.* describes culturing *Salmonella typhimurium*, and Ohyama *et al.* describe culturing *E. coli*. As understood in the art and confirmed by the teachings of these references, media used to culture *Salmonella* and *E. coli* does not typically contain Tween or any type of detergent. Given that the skilled artisan would appreciate that different microorganisms have different optimal media, the skilled artisan would elect to use a media established for growth of the organism of interest and would not be motivated to substitute or add additional components of media formulated for different microorganisms. Accordingly, neither Marino *et al.* nor Ohyama *et al.* would be motivated to add a detergent to the media described in these references. Furthermore, while clumping may be a concern when culturing *Mycobacterium*, it is not such a concern for other microorganisms,

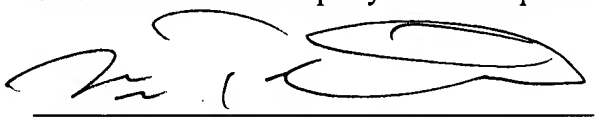
including *Salmonella* and *E. coli* (hence, no detergent is typically included in growth media for these bacteria). Accordingly, the skilled artisan would not be motivated to include a detergent, such as Tween, in the media of the present invention. Since none of the cited references teach or suggest any advantage or desirability of modifying the teachings of the references to produce the claimed compositions, Applicants submit that the Action fails to establish a *prima facie* case of obviousness and respectfully request that this basis of rejection be withdrawn.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants submit that all of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



William T. Christiansen, Ph.D.
Registration No. 44,614

WTC:jto

Enclosure:
Postcard
Notice of Appeal

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

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